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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,868	03/30/2001	Robert K. DiNello	22203-712	7040

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EXAMINER
NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
1641	7

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,868	DINELLO ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *1-27 and 46-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 1-27 and 46-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

2. Applicant's election without traverse of Group II, claims 28-45 in Paper No. 6 is acknowledged. This application contains claims drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. Claims 28-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-45 are vague and indefinite with respect to the placement of the different zones on the test strip. According to Webster's dictionary "distal" means "located far from the origin or line of attachment"; and "proximal" means "near the central part of the body or a point of attachment", using these definitions, the claims are confusing because it is unclear which zone is located where and how the buffer and the sample diffuses. It appears from other descriptions in the specification and the drawings that the words "proximal" and "distal" are being used instead of "left" and "right" and this is confusing. It is requested that Applicant clearly recite the location of each zone relative to all of the other zones on the test strip and how the sample and buffer travels relative to these zones. For example, it would be less confusing if

the zones of the test strips are also designated as first, second and third (according to their order from left to right) in addition to their functional names.

Claims 29-35 and 43-45 are confusing because they appear to be limitation of a device and not a method.

Claims 29 and 32 are confusing because it is unclear where the zone containing the second analyte binding agent is located because it is unclear what the point of reference is for the recitation of "proximal" and "distal". See the definition above.

Claim 33 is confusing because it is unclear where the sample addition zone is positioned on the test strip.

Claims 34 and 35 are confusing because it is unclear where the various zones are located. Claims 34 and 35 are also vague and indefinite because it is unclear how two different liquid specimen, i.e. the sample and the buffer solution, added to different ends of the sample device is able to diffuse toward each other and not in one direction, either to the left or right relative to their own location. What property does the test strip possess that allow this to occur

Claims 36-39 are confusing because there appear to unclear how 10 liters of a buffer can be added to a test strip. These recitations appear to be typos. Correction is required.

Claim 40 is confusing because it is unclear how the buffer comprises the sample.

Claim 41 is confusing because it is unclear how the buffer is the same with the sample.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 28-45 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Clark (USP 5,726,010).

Clark discloses a reversible flow chromatographic binding assay device and method comprising, from left to right, an absorbent reservoir, a first region for receiving a fluid sample, a second region having an immobilized analyte capture agent, a third region for application of a liquid wash buffer, and a fourth region for application of a detector reagent. In one specific embodiment, the device also includes a liquid soluble barrier between the absorbent and the first region. The barrier is positioned to prevent flow of the liquid reagent from the supply to the absorbent reservoir until after the sample has flowed from the first region through the second region . At that point, the barrier dissolves permitting the reagent to flow through the second region and into the absorbent reservoir. See page 4, lines 7-20; page 5, lines 3-9; lines 13-20; page 6, lines 13-21; page 6, line 30 through page 7, line 12. In use, sample and liquid reagent is contacted with the flow matrix either sequentially or simultaneously, analyte in the sample binds to latex labeled capture agent and is captured and immobilized in the test areas. Next, the absorbent reservoir is contacted with the saturated flow matrix, either mechanically or by dissolution of a soluble film, thereby reversing the fluid flow. Finally, detector and/or wash solution is delivered to the flow matrix. The overall sequencing of the method steps is controlled by the flow of the liquid within the flow matrix and the physical positioning of the

sample, and liquid reagent entry points relative to the position of the deposited labeled specific binding reagents and the analyte capture reagent. See page 12. Clark discloses an absorbent reservoir positioned adjacent to the sample entry means that is fluidically coupled to the flow matrix in order to promote liquid flow in the reverse direction.

6. Claims 28-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Thayer et al (USP 6,528,323 B1)

> The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Thayer discloses a test strip and method for detecting an analyte. Thayer discloses a test strip comprising a sample addition zone, an absorbent zone proximal to the sample addition zone; one or more test zones distal to the sample addition zone, at least one of the test zones including a first analyte binding agent immobilized therein, and a terminal sample flow zone distal to the one or more test zones. The absorbent zone being positioned relative to the sample addition zone and having an absorption capacity relative to the other zones of the test strip such that a distal diffusion front of a sample added to the sample addition zone diffuses from the sample addition zone to a distal diffusion point within the terminal sample flow zone and then reverses direction and diffuses proximal relative to the one or more test zones. See columns 1 and 2. Thayer teaches that in use, sample is delivered to the sample addition zone which causes a distal diffusion front of the sample to diffuse in a distal direction to one or more test zones, and to diffuse to a terminal sample flow zone distal to the one or more test zones, change direction and diffuse to a position proximal to the one or more test zones; delivering a conjugate

buffer to the test strip at a position distal to the terminal sample flow zone, and detecting the second analyte binding agent immobilized to the test zone. See column 3, lines 1-16. Thayer teaches that the conjugate buffer may be added to the test strip at the same time that sample is added to the test strip, or before or after sample is added. See column 3, lines 25-35. Thayer also teaches control zones with control binding agents. See column 3, lines 37-48.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 28-35 and 40-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-41 of U.S. Patent No. 6,528,323 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and '323 claims a method for detecting an analyte using a test strip where the sample diffuses in a first flow direction toward an absorbent pad and in a second, different flow direction to one or more test zones. After diffusing past the test zones, the sample reverses flow and diffuses back toward the absorbent pad. A conjugate

buffer is added to a buffer addition zone causing a second analyte binding agent to diffuse in the first flow direction pas the test zones.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,750,333
US 6,007,999
US 6,136,610

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
AU 1641

March 27, 2003